

DEC 1 2005

## 510(k) Summary GraftCage™ ACX

<b>October 28, 2005</b>	
<b>Submitted By:</b>	<b>Osteotech, Inc.</b>
<b>Address:</b>	<b>51 James Way Eatontown, New Jersey 07724</b>
<b>Telephone:</b>	<b>(800) 537-9842, Ext. 6324</b>
<b>Contact Person:</b>	<b>Christopher Talbot Director, Regulatory Affairs</b>
<b>Subject Device</b>	
<b>Trade Name:</b>	<b>GraftCage™ ACX</b>
<b>Common Name:</b>	<b>Vertebral Body Replacement Device</b>
<b>Classification Name:</b>	<b>Spinal Intervertebral Body Fixation Orthosis</b>

### **Device Description:**

The GraftCage™ ACX is a device designed to replace a thoracic or lumbar vertebral body and to support axial compression loads following vertebrectomy for the treatment of spinal tumors and in cases of spinal trauma/fracture. The GraftCage™ ACX is made from implantable PEEK-OPTIMA® (polyetheretherketone) polymer.

The GraftCage™ ACX is basically rectangular in shape. One central (axial) fenestration and one fenestration on each lateral aspect (on certain sizes) provide locations for the addition of bone grafting material. The superior and inferior aspects have ridges that resist expulsion and /or migration after implantation. The device offers lordotic and non-lordotic i.e., parallel configurations. The posterior aspect of both design configurations is tapered, or bulleted, for ease of insertion.

A single threaded hole at the posterior aspect interfaces with the insertion tool. The insertion tool is a shaft attached to a handle. The shaft has a threaded end that matches the threaded hole on the GraftCage™ ACX and allows the surgeon to hold the GraftCage™ ACX while implanting it into the patient.

### **Intended Use:**

The GraftCage™ ACX is a vertebral body replacement device intended to replace a collapsed, damaged, or unstable vertebral body in the thoracic or lumbar spine (T1-L5). The GraftCage™ ACX is indicated for a partial or total vertebrectomy for cases of tumor or trauma (i.e., fracture). The GraftCage™ ACX is intended to achieve anterior decompression of the spinal cord and neural tissues and to restore the height of a collapsed vertebral body.

The GraftCage™ ACX is intended for use with supplemental internal spinal fixation systems that are cleared by FDA for use in the thoracic and lumbar spine. These systems include posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems. The use of bone grafting material with the GraftCage™ ACX is optional.

### **Comparison to Predicate:**

The GraftCage™ ACX claims substantial equivalence to:

- 1) Osteotech, Inc. VBR, K012254
- 2) DePuy AcroMed VBR System, K030833/K031635;
- 3) Spinal Concepts Fortitude Vue Vertebral Body Replacement Device, K05100; and
- 4) Implex Corporation Hydrocel Vertebral Body Replacement System, K010378.

This claim of substantial equivalence is intended to reflect FDA's definition of substantial equivalence as defined by 21 CFR Part 807, Subpart E and is not intended to reflect a claim of substantial equivalence in terms of intellectual property.

The GraftCage™ ACX and the predicate devices have the same intended use and similar technological characteristics. Performance data demonstrates that the GraftCage™ ACX meets or exceeds functional requirements for a vertebral body replacement device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 1 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Christopher Talbot  
Director Regulatory Affairs  
Osteotech, Inc.  
51 James Way  
Eatontown, New Jersey 07724

Re: K053080  
Trade/Device Name: GraftCage™ ACX  
Regulation Number: 21 CFR 888.3060  
Regulation Name: Spinal intervertebral body fixation orthosis  
Regulatory Class: II  
Product Code: MQP  
Dated: November 1, 2005  
Received: November 2, 2005

Dear Mr. Talbot:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours, -

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized flourish at the end.

Mark N. Melkerson  
Acting Director  
Division of General, Restorative,  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**INDICATIONS FOR USE  
STATEMENT****510(k) NUMBER (IF KNOWN):** K053080**DEVICE NAME:** GraftCage™ ACX**INDICATIONS FOR USE:**

The GraftCage™ ACX is a vertebral body replacement device intended to replace a collapsed, damaged, or unstable vertebral body in the thoracic or lumbar spine (T1-L5). The GraftCage™ ACX is indicated for a partial or total vertebrectomy for cases of tumor or trauma (i.e., fracture). The GraftCage™ ACX is intended to achieve anterior decompression of the spinal cord and neural tissues and to restore the height of a collapsed vertebral body.

The GraftCage™ ACX is intended for use with supplemental internal spinal fixation systems that are cleared by FDA for use in the thoracic and lumbar spine. These systems include posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems.

The use of bone grafting material with the GraftCage™ ACX is optional.

Prescription Use  X   
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use     

**PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER  
PAGE IF NEEDED.**

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  

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(Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

**510(k) Number**  K053080

C-1

Page 1 of 1